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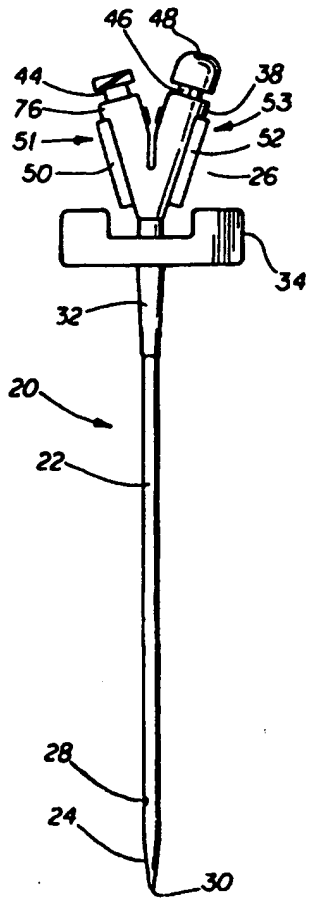
(54) Title: DUAL LUMEN CATHETER HAVING VALVES

(57) Abstract

The invention provides a dual lumen vascular access catheter having an elongate main body and a compact outer structure attached to the main body. The outer structure includes a housing and valves in the housing. Actuators are attached one to each valve and operable to open and close the valves. The actuators are stored along sides of the housing with the valves closed and project visibly from the housing when rotated in either direction to open the valves.



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DESCRIPTION

DUAL LUMEN CATHETER HAVING VALVES

TECHNICAL FIELD

This application relates to a multi-lumen catheter used in procedures requiring intrusion into the blood circulation system of a patient, and normally referred to as vascular access catheters. More particularly, the invention relates to such catheters having a connection structure at the proximal end in the form of a compact housing which includes valves operable independently to control flows through the respective lumens.

BACKGROUND ART

Vascular access catheters have been developed as single lumen, dual lumen or multi-lumen catheters and are used for a variety of procedures, all of which involve intrusion into the blood circulatory system. The main body of the catheter is designed for placement in a blood vessel and the body is permanently attached at an outer, or proximal end, to a connector which couples each of the lumens to one of a pair of extension tubes. It is common practice for these extension tubes to be flexible tubing and each of the tubes is fitted with a luer lock connector at its free end for attachment to a fluid line. The connectors can be capped to close and seal the lumens when the catheter is not in use and a further seal is usually provided on each tube in the form of a clamp engaged about the tube and operable to squeeze the tube shut and hold it in this condition.

The clamps form a second line of defence and they are made necessary because it is possible that the luer lock and its cap can fail due to misuse or to flaws created during manufacture. It is evident that should both the luer lock and the clamp fail while the catheter is in place, the patient is at risk of bleeding to death or suffering an air

embolism if the failure is not detected very quickly.

The combination of a flexible tube and a clamp is not entirely satisfactory. The most serious problem with the arrangement is that because the clamp closes the tubes by a pinching action, the tube may take a "set" and not recover when the clamp is released, especially if the clamp has been in place for a prolonged period. In extreme cases, the catheter has to be removed because the set has restricted flow and the tube is no longer patent.

Tube failure is most prevalent on catheters that have thermoplastic tubular extensions made from polyurethane (PU). Also the problem is exacerbated by the fact that such extensions are attacked in a mild way by organic solvents such as alcohol that is always present in heparin, the anti-coagulant of choice used in catheters to maintain the patency of the catheter when not in use.

An alternative to PU is silicone rubber which is not attacked by solvents such as alcohol. Consequently the walls will not stick to one another and this combined with the good rebound properties make it suitable for use as extension tubes. Although some manufacturers do use silicone rubber extensions for this reason, there is a different problem which has resulted in silicone rubber being superseded by PU. This problem relates to the fact that silicone is not thermoplastic and does not bond readily. Consequently if silicone rubber is to be used the tubes must be engaged using a friction fit alone and of course such a fit is subject to disconnection and adds another risk factor to the use of the catheter. It is therefore most common to accept the lesser disadvantages of PU extensions because they can be permanently bonded during assembly of the catheter.

There are other problems associated with the use of tubes and clamps. The tubes and the structure needed to attach the tubes to the main body of the catheter constitutes an unwieldy and bulky

assembly. Clamps have been known to become disengaged by a minor impact and such disengagement is visually evident only by close examination. Consequently, the structure has been made sufficiently large to keep the clamps away from one another and in exposed positions where they can be examined easily.

Attempts have been made to design catheters having less bulky structure outside the intrusion site in order to both provide more security when the catheter is not in use, and also to provide less discomfort and inconvenience for the patient. One approach is illustrated in U.S. Patent No. 5324274. This patent illustrates a series of embodiments which have a common characteristic in that two valves are shown having actuators lying essentially in a common plane. The structures vary but all require that space be provided for the actuators to be operated independently without interference. This leads to conflicting design criteria when minimizing the bulk of the external structure. Firstly to minimize bulk the actuators and associated valves should be as close to the main body of the catheter as possible. This contrasts with the second criterion which dictates that for ease of actuation, and to ensure that an actuator is not moved accidentally when moving the other actuator, the actuators should be spaced from each other and this results in a larger structure needed to give them separation and to accommodate the actuation without having the actuators project from the structure when stored.

Another consideration comes into play in many procedures. During use, the catheter may become inefficient due to some form of restriction to flow caused, for example, by occlusion of one of the ports in the catheter. To correct this the catheter is rotated about its axis through about 180 degrees to move any occluded port away from the blood vessel wall or whatever us causing the reduction in flow. If the catheter is to be used in a procedure where such manipulation is

desirable, then the actuator must be available from both sides of the catheter so that it can be used no matter how the catheter lies against the patient at the intrusion site.

It is among the objects of the present invention to provide a vascular access catheter having a compact external structure.

A further object is to provide a catheter having valve actuators located for independent operation and which give the same appearance for use whether or not the catheter is rotated through 180 degrees.

It is also an object of the invention to provide external structure having valve actuators which, when in the stored position, have reduced risk of accidental operation.

DISCLOSURE OF THE INVENTION

A catheter of the type used for use in procedures requiring vascular access, the catheter having an elongate main body defining lumens and including proximal and distal ends, the distal end having ports for flow to and from the lumens, and outer structure at the proximal end providing connectors for flow to and from the lumens, the catheter being characterized by the outer structure being compact and comprising: a housing including independent channels connected one to each of the lumens and diverging as they extend away from the main body, connectors being in fluid communication one with each of said channels, valves one in each of the channels adjacent the connectors, and actuators coupled one to each of the valves, the actuators lying against the housing and extending from the valves axially towards the main body when stored with the valve closed, whereby the valves can be opened fully by rotating the actuators through 90 degrees in either direction to provide a visual indication that the valves are open to flow through the channels.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood with reference to the following description and drawings, in which:

Fig. 1 is a frontal view showing the actual size of an exemplary catheter according to a prepared embodiment of the invention;

Fig. 2 is a view similar to Fig. 1 and showing that portions of the catheter broken away to expose internal detail at a proximal end of the catheter;

Fig. 3 is a side view drawn in the direction of arrow "A" shown in Fig. 2 and illustrating the movement of an actuator; and

Fig. 4 is a view similar to Fig. 2 but showing only a portion of an alternative embodiment of catheter.

BEST MODE FOR CARRYING OUT THE INVENTION

Reference is made first to Fig. 1 which illustrates an exemplary catheter incorporating a preferred embodiment of the invention and designated generally by the numeral 20. The catheter includes an elongate main body 22 extending from a tip 24 at the distal end to outer structure 26 at the proximal end and main body is a dual lumen of any suitable form typically having intake openings such as opening 28 and a return opening 30 at the tip. The exact form of the main body is not critical to the invention.

The main body is strengthened adjacent the proximal end by a sleeve 32 which meets a rotatable suture wing 34 as is conventional in catheters of this type. As can be seen in Fig. 2, this is done by providing a waist 36 during assembly and the suture wing rotates on this waist located in place by the enlargements to either end of the waist. Returning to Fig. 1, it will be seen that the structure 26 consists of a housing 38 which is generally Y-shaped and as will be

explained, defines channels 40, 42 (Fig. 2) communicating with the main body 22 for fluid flow into and out of the lumens in the main body. The housing accommodates a pair of luer connectors 44, 46 for connection to external equipment. Fig. 1 shows one of the luer connectors 46 having a cap 48 of the type used when the catheter is not in use. Also in Fig. 1 can be seen a pair of actuators 50, 52 associated with valves 51, 53 which are in the form of levers and in the storage position of Fig 1, these levers extend generally axially along sides of the housing 38. The actuators are operable to open the valves which are in the closed position in Fig. 1 and this will be described in more detail with reference to Fig. 2. For the moment it is sufficient to understand that they can be rotated and when they are rotated they stand out from the housing 38 for ready visual indication of the condition of the valves.

It is important to note with reference to Fig. 1 the proportions of the other structure in relation to the catheter as a whole. The structure permits the use of actuators quite close to the suture wing 34 because the arrangement permits independent use with minimal likelihood of accidental movement of the other actuator. This contrasts with prior structures where the length of the housing had to be lengthened to ensure that the actuators were separated. The actuators shown in Fig. 1 blend into the overall structure and are less likely to be operated by accident, and when the catheter is not attached to equipment, the compact nature of the outer structure is such that it will present minimal discomfort and inconvenience to the patient.

Reference is next made to Fig. 2 to describe details of the outer structure 26. It will be seen here that the channels 40, 42 pass through cylindrical chambers 54, 56 which have axes generally in a common plane. The cylindrical chambers terminate at respective convergent walls 58, 60 provided to trap rotary valve barrels such as

barrel 62. It will be seen that the barrel includes a neck 64 which complements the convergent wall 58 to snap fit the barrel in place inside the cylindrical chamber.

As is conventional in rotary valves, the barrel includes an opening 66 positioned so that when the valve is operated, this opening is aligned with channel 42 to permit flow, and when the actuator is moved from the active position to the stored position shown in Fig. 2, the opening is out of alignment so that flow is prevented.

The barrel 62 is integrally attached to the lever or actuator 52 which is located in the stored position by engagement over a raised detent 70, and there is a similar detent 72 on the opposite side of the housing to accommodate the other actuator 50. Of course the lever has a recess 74 (Fig. 3) provided to accommodate this detent. As a result, there is a positive location of the actuator in the stored position to further ensure that the actuator is not moved accidently.

The outer structure 26 is completed by the inclusion of the luer connectors 44, 46 which are put in place during the moulding operation of the housing 38.

The barrels 62 of the rotary valves ride directly in the cylindrical chambers 54, 56 of the housing 38. It is preferable that plastics materials be selected to give some compliancy for better sealing between these parts. It is anticipated that the housing 38 will be made from polyurethane which matches the material of the main body 22, and due to the similar plastic characteristics, makes it possible to form an essentially integral structure. The barrels 62 of the rotary valves would preferably be of polyamide (sold under the trademark NYLON.)

Outer housing 38 is essentially of fixed shape, but there will be some resilience and this is enhanced by the inclusion of a slot 74 between branches of the housing. However this is an optional

characteristic that is not essential. It does of course also have the advantage also that it reduces the amount of material in the housing and therefore the weight of the structure.

Reference is next made to Fig. 3 which illustrates the operation of the rotary valve in the housing. This view is drawn on arrow "A" of Fig. 2 and shows the actuator 52 both in a stored position and in two active positions shown in ghost outline. These positions are possible because the actuator can be moved to the right or to the left as drawn in Fig. 3 and results in positions which are essentially at 90 degrees to the stored position. As seen in Figs. 1 to 3, the actuator can only be moved until it meets a shoulder 76 provided to limit movement and ensure that the valve is the active or open position. A very important consideration is that when the actuator is in the open position, it is proud of the housing and consequently it is very clearly open and anyone inspecting the structure can see that it is open. Similarly, in the stored or closed position, the actuator is positively located using one of the detents 70, 72 where it blends into the overall shape of the housing. It is then evidently in the stored position with the valve closed.

It will be evident from a review of these drawings that the overall length of the outer structure is minimized due to the location of the actuators and in fact, the length is dictated by having actuators that are readily operable. It is found that if the actuators could be shorter, then the arrangement could be compressed into a smaller form bringing the valves closer towards the main body 22.

It would also be possible to reduce the overall size of the housing by reducing the material necessary to lock the luer connectors 44, 46 in the assembly. Of course these connectors must stand sufficiently proud of the housing 38 to ensure proper connection of tubing, etc. and this is an essential part of the assembly. However, it

will be seen in Fig. 2 a substantial amount of material is used in locking the luer connector in position and it has been found that this can be reduced by using a secondary embodiment such as that shown in Fig. 4. Here a luer connector 80 is formed to include a through opening 82 which is proportioned to match a channel 84 and a transverse opening 86 is provided in alignment with a cylindrical chamber 88 in a housing 90. This allows the luer connector to be locked in place by an end lip 92 in the material of the housing on the same side of the main body 22 rather than on the opposite side as shown in Fig. 2. This special form of luer connector must of course be proportioned to match the barrel of the actuator.

These and other embodiments of the invention are within the scope of the invention as described and claimed.

INDUSTRIAL APPLICABILITY

Catheters according to the invention can be made using established extrusion, moulding and forming techniques commonly used in modern catheter manufacture. The catheter would be used in medical techniques requiring intrusion to withdraw blood from a blood vessel for treatment before returning the blood to the same blood vessel.

INDEX OF REFERENCE SIGNS

20	Catheter	22	Main body
24	Tip	26	Outer structure
28	Opening	30	Opening
32	Sleeve	34	Suture wing
38	Housing	40	Channel
42	Channel	44	Luer connector
46	Luer connector	48	Cap
50	Actuator	51	Valve
52	Actuator	53	Valve
54	Chamber	56	Chamber
58	Convergent wall	60	Convergent wall
62	Barrel	64	Neck
66	Opening	70	Detent
72	Detent	74	Recess
80	Connector	82	Opening
84	Channel	86	Opening
88	Chamber	90	Housing
92	Lip		

CLAIMS

1. A catheter (20) of the type used for use in procedures requiring vascular access, the catheter having an elongate main body (22) defining lumens and including proximal and distal ends, the distal end having ports (28, 30) for flow to and from the lumens, and outer structure (26) at the proximal end providing connectors (44, 46) for flow to and from the lumens, the catheter being characterized by the outer structure being compact and comprising: a housing (38) including independent channels (40, 42) connected one to each of the lumens and diverging as they extend away from the main body, the connectors (44, 46) being in fluid communication one with each of said channels, valves (51, 53) one in each of the channels adjacent the connectors, and actuators (50, 52) coupled one to each of the valves, the actuators lying against the housing and extending from the valves axially towards the main body when stored with the valve closed, whereby the valves can be opened fully by rotating the actuators through 90 degrees in either direction to provide a visual indication that the valves are open to flow through the channels.

2. A catheter as claimed in claim 1 and further characterized in that the valves are rotary valves having barrels (62) with axes of rotation in a common plane.

3. A catheter as claimed in claim 1 and further characterized in that said connectors are luer connectors.

4. A catheter as claimed in claim 1 and further characterized in that said housing is injection moulded and in which said connectors are luer connectors partly embedded in the injection moulded housing.

5. A catheter as claimed in claim 1 and further characterized in that the housing includes stops (76) to limit the rotation of the actuators to 90 degrees in both directions from the stored position.

6. A dual lumen catheter as claimed in claim 4 and further characterized in that the valves are rotary valves having barrels (62) with axes of rotation in a common plane.

7. A catheter as claimed in claim 1 and further characterized in that the actuators blend into the overall housing to limit the possibility of accidental operation with the valves closed.

8. A catheter as claimed in claim 1 and further characterized in that the housing and actuators include detents (70, 74) to locate the actuator in the stored position.

9. A catheter as claimed in claim 1 and further characterized in that there are two lumens in the catheter.

AMENDED CLAIMS

[received by the International Bureau on 6 August 1996 (06.08.96); original claims 1-9 replaced by amended claims 1-7 (2 pages)]

CLAIMS

1. A catheter (20) of the type used for use in procedures requiring vascular access, the catheter having an elongate main body (22) defining lumens and including proximal and distal ends, the distal end having ports (28, 30) for flow to and from the lumens, and outer structure (26) at the proximal end providing connectors (44, 46) for flow to and from the lumens, the catheter being characterized by the outer structure being compact and comprising: a housing (38) including independent channels (40, 42) connected one to each of the lumens and diverging as they extend away from the main body, the connectors (44, 46) being in fluid communication one with each of said channels, valves (51, 53) one in each of the channels adjacent the connectors, the valves being operable about axes lying in a common plane, and actuators (50, 52) coupled one to each of the valves, the actuators lying against the housing and extending from the valves axially towards the main body when stored with the valve closed, whereby the valves can be opened fully by rotating the actuators through 90 degrees in either direction so that the actuators stand out from the outer structure at about 90 degrees to said common plane to provide a visual indication that the valves are open to flow through the channels.

2. A catheter as claimed in claim 1 and further characterized in that said connectors are luer connectors.

3. A catheter as claimed in claim 1 and further characterized in that said housing is injection moulded and in which said connectors are luer connectors partly embedded in the injection moulded housing.

4. A catheter as claimed in claim 1 and further characterized in that the housing includes stops (76) to limit the rotation of the actuators to

90 degrees in both directions from the stored position.

5. A catheter as claimed in claim 1 and further characterized in that the actuators blend into the overall housing to limit the possibility of accidental operation with the valves closed.

6. A catheter as claimed in claim 1 and further characterized in that the housing and actuators include detents (70, 74) to locate the actuator in the stored position.

7. A catheter as claimed in claim 1 and further characterized in that there are two lumens in the catheter.

STATEMENT UNDER ARTICLE 19

Applicant has considered the search report in detail and of course is aware of the reference, i.e. U.S. Patent 5,324,274 which is an earlier patent obtained by one of the inventors in the present application.

In order to better define the present invention, language has been introduced into claim 1 to identify the location and action of the valves and actuators. It is believed that this distinction clearly defines the present invention over the earlier Martin patent.

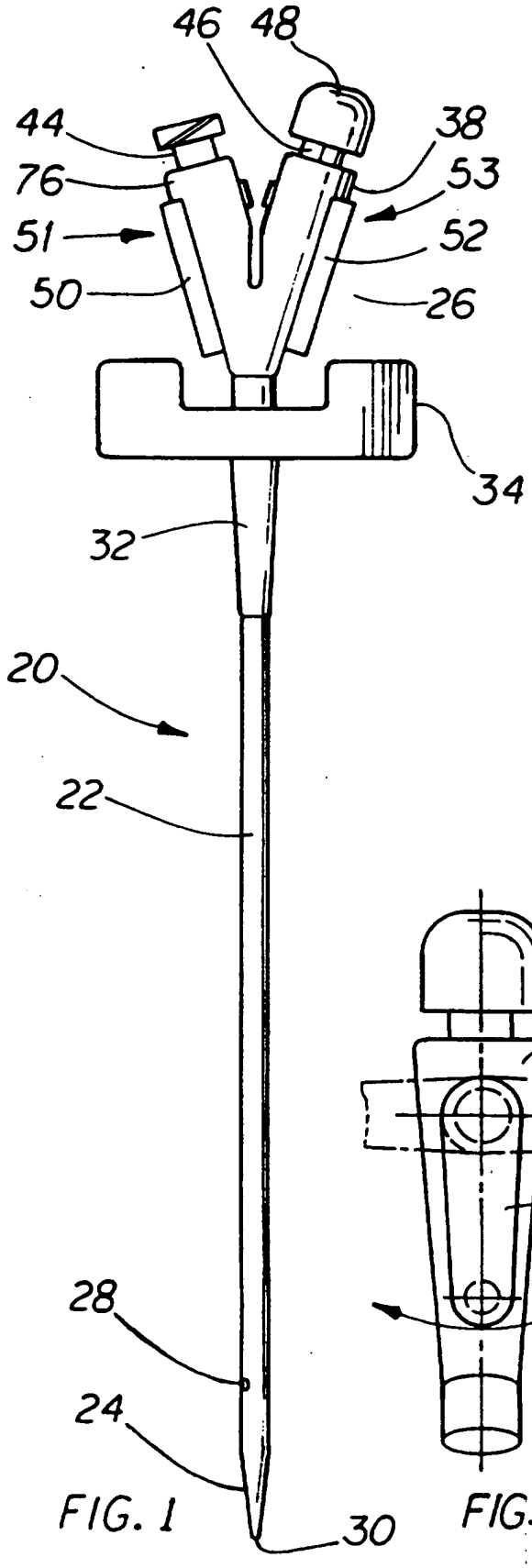

FIG. 1

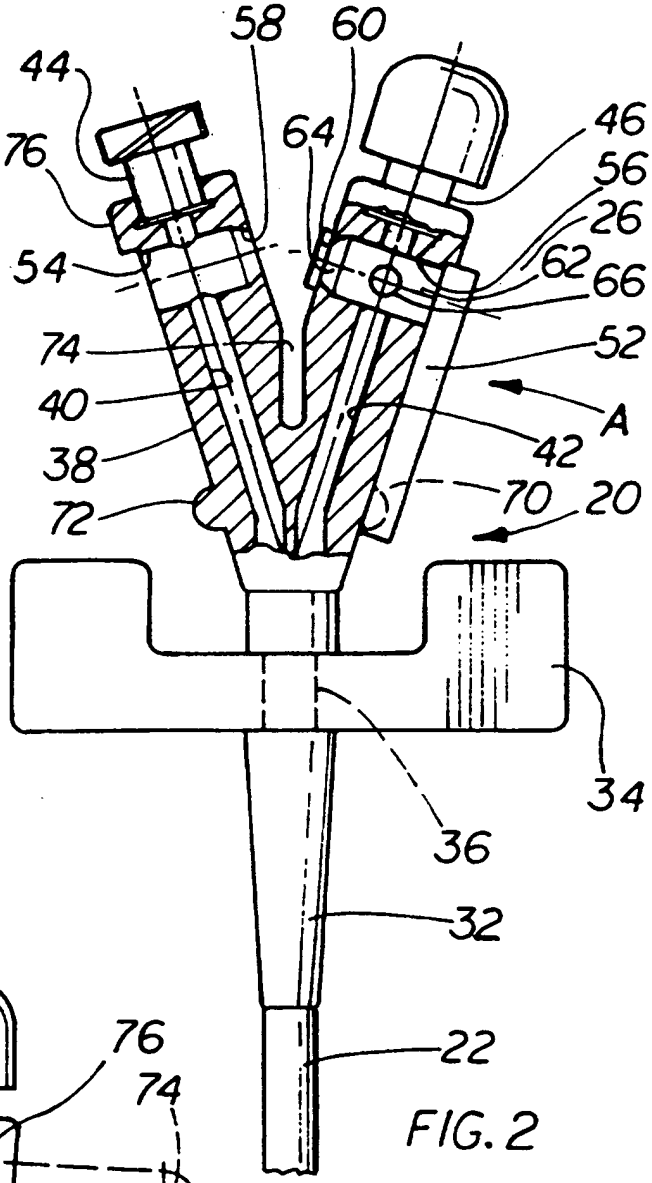

FIG. 2

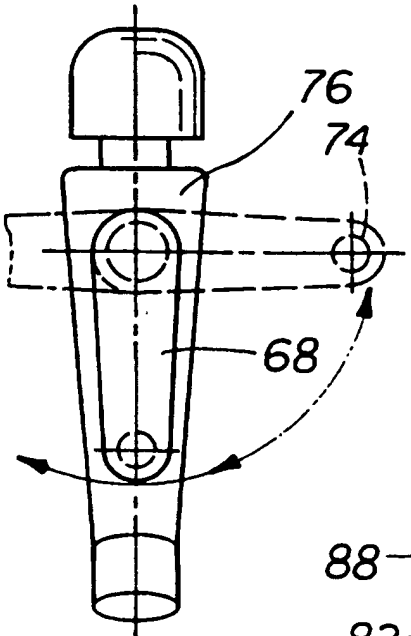

FIG. 3

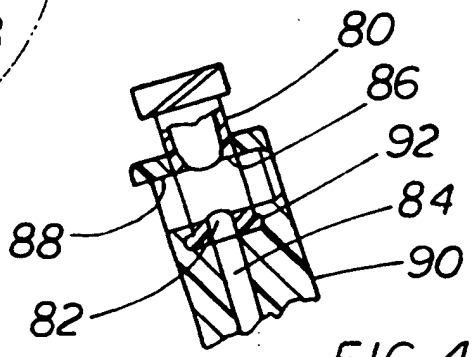

FIG. 4

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/CA 96/00160

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00 A61M5/158

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,5 324 274 (MARTIN) 28 June 1994 cited in the application * The Whole Document * -----	1-9

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/CA 96/00160

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-5324274	28-06-94	US-A- 5472432	05-12-95